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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/285,429	04/02/1999	BRET A. SHIRLEY	5784-9	3707

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EXAMINER

KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 04/17/2002

20

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/285,429

Applicant(s)

SHIRLEY ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 January 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-14 and 21-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 21-28 and 31-34 is/are allowed.
- 6) ☒ Claim(s) 10-14, 29 and 30 is/are rejected. 1-14 ?
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 1-14 and 21-34 are pending.

Applicants' amendment filed January 24, 2002 (Paper No. 19) is acknowledged, and applicant's response has been fully considered.

### **Rejection Withdrawn**

#### ***Claim Rejections - 35 USC § 112***

2. The previous rejection of claims 1-14 and 21-34 under 35 USC § 112, first paragraph, regarding "pharmaceutically active agent", "biologically active variant of human IGF-1" and "succinate causes less pain on injection", is withdrawn in view of applicants' response at pages 2 and 3 in Paper No. 19.
3. The previous rejection of claims 1-14 and 21-34 under 35 USC § 112, second paragraph, regarding the term "substantially", is withdrawn in view of applicants' response at page 4 in Paper No. 19. The term "consists substantially of" is treated as "comprising".

#### ***Claim Rejections - 35 USC § 103(a)***

4. The previous rejection of claims 1-14 under 35 USC § 103(a), as being unpatentable over Clark *et al.* (U. S. Patent 5,374,620) in view of Bontempo *et al.* (EP 0284249) or Acott *et al.* (U. S. Patent 5,985,830), is withdrawn in view of applicants' response at pages 5-8 in Paper No. 19.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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5. Claims 1-10, 13 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-10, 13 and 14 are indefinite because of the use of “at least one pharmaceutically active agent”. The term “at least one pharmaceutically active agent” renders the claim indefinite, it is unclear how many pharmaceutically active agents are included in the pharmaceutical composition, and what compound is as to pharmaceutically active agent. Claims 2-10, 13 and 14 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

In response, applicants indicate the specification states pharmaceutically active agents include any pharmaceutically effective compound that is compatible with succinate buffer. The argument is not found persuasive because the claim does not specify how many active agents are included and which active agent(s) are in the pharmaceutical composition, thus, it is not clear what components are in the composition.

6. Claims 9, 10, 29 and 30 are indefinite because of the use of the terms “a sufficient concentration”, “at least one tonicifying agent” and “such that”. The terms “a sufficient concentration”, “at least one tonicifying agent” and “such that” render the claim indefinite, it is not clear what concentration of tonicifying agent is for a pharmaceutical composition being isotonic, how many tonicifying agents are in the pharmaceutical composition, and whether the limitations following the phrase “such that” are part of the claimed invention. Claims 10 and 30 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

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In response, applicants indicate the specification explains how to adjust a solution using a tonicifying agent such that it is isotonic (page 4 of the response). The argument is not found persuasive because the claim does not specify how many tonicifying agents and what concentration are included in the in the composition, and whether the composition is isotonic or not.

7. Claims 11 and 12 are indefinite because of the use of the term “a biologically active variant thereof”. The term “a biologically active variant thereof” renders the claim indefinite, it is unclear what amino acid sequence the variant of human IGF-1 has.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102(b) that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-3, 6-10, 13 and 14 are rejected under 35 U.S.C. 102(b) as anticipated by Bontempo *et al.* (EP 0284249).

Bontempo *et al.* teach a lyophilized lymphokine composition for therapeutic administration comprises a pharmaceutical active agent,  $\alpha$ -2 interferon (page 3, line 33), a succinate buffer (mixture of succinic acid and sodium succinate; page 4, lines 26-27) at 50 mM concentration (page 5, line 19), which is about 30 or 40 mM of succinate (claims 1, 2 and 3), an isotonic agent sodium chloride (page 4, lines 15-16; claims 9 and 10), a bulking agent, a stabilizer and a dispersant (Examples 1-4). The solution has a pH about 4.0 to about 8.0 (page 4, lines 20-22; claims 6-8 and 13), and is lyophilized (page 5, lines 2-10; claim 14).

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9. Claims 1-8, 13 and 14 are rejected under 35 U.S.C. 102(b) as anticipated by Hwang-Felgner *et al.* (U. S. Patent 5,151,265).

Hwang-Felgner *et al.* teach a liquid pharmaceutical composition comprises  $\gamma$  interferon (column 2, line 43), a succinate buffer (mixture of succinic acid and sodium succinate; column 3, lines 9-12) at concentration of succinic acid (0.27 mg/ml, 2.3 mM; column 3, line 61; Example 1) and disodium succinate (0.73 mg/ml, 4.5 mM; column 3, line 62; total succinate =  $2.3 + 4.5 = 6.8$  mM), which is about 10 mM of succinate (claims 1-5). The solution has a pH about 4.0 to 6.0 (column 3, lines 3-5; claims 6-8), and the liquid formulation of  $\gamma$  interferon has a greater shelf life than the lyophilized formulation (column 4, line 9-column 5, line 10; Tables 1 and 2; claims 13 and 14).

10. Claims 1-8 and 13 are rejected under 35 U.S.C. 102(b) as anticipated by Sato *et al.* (U. S. Patent 4,605,555).

Sato *et al.* teach a pharmaceutical composition comprises human interferon (column 2, lines 50-53), and an organic acid buffer such as a succinate buffer (mixture of succinic acid and sodium succinate) at concentration of 0.01-0.2 mole/kg composition (column 3, lines 10-39; claim 4 in the patent), which is about 10-200 mM of succinate, and the pH of the buffer is 3-6 (claims 1-8 and 13).

11. Claims 1-3 and 13 are rejected under 35 U.S.C. 102(b) as anticipated by Olefsky *et al.* (WO 96/40894).

Olefsky *et al.* teach a liquid pharmaceutical composition comprises protein kinase C antagonist, a succinate buffer at concentration of 0.05 M, which is about 30 or 40 mM of

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succinate (page 23, lines 5-15; claim 1-3), and the pharmaceutical carrier can be aqueous solution (claim 13).

*Conclusion*

12. Claims 1-14 and 29-30 are rejected. It appears claims 21-28 and 31-34 are free of prior art, thus are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CMK*  
Patent Examiner

*Karen Cochrane Carlson Ph.D.*  
KAREN COCHRANE CARLSON, PH.D.  
PRIMARY EXAMINER

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April 14, 2002